

CD77

Chemical Indicator

For monitoring Gamma Radiation sterilization processes



Usage

Control of Gamma Radiation sterilization processes.

Conditions: ≥ 10 kGy.

Applicable Regulation

ISO 11140-1:2014

Product Classification

Class 1, according to risk.

Authorization

Designed under Quality Management Systems ISO 9001:2008 and ISO 13485:2012. ANMAT (Argentinean National Administration of Drugs, Food and Medical Technology) PM 1614-4.

Characteristics

Type 1 Chemical Indicator.

Self-adhesive label (dot) printed with indicator ink.

Size: 15 mm of diameter

Initial color: **yellow**

Final color: **red**

100 % Toxic Heavy Metals free



Environmental conditions during manufacture

15-30 °C (room temperature), RH 30-80 %.

Storage conditions

T = 10-30 °C, RH 30-80 %, keep out of direct light.

Transportation conditions

Storage conditions should be strictly followed. Transport in closed and reinforced boxes in order to avoid damages. Transportation of this product does not represent a risk for health.

Shelf-life

5 years

Packing

1000 labels per roll in individual boxes.

Packing information: product description, process for intended use, operating instructions, classification according to regulation, manufacturer information and data on box's label.

Weight per box: 55,9 g

Labelling

On roll's cone: batch number, expiration date and manufacturer's name.

On product's box: product code, presentation, batch number and expiration date.

Possible target markets

Healthcare, Food, Pharmaceutical and Medical industries.

Other important information (optional)

Read product's directions for use thoroughly before use.

Note: When necessary, limits for each product's parameters should be specified.

Description of identified and/or predictable risks which could represent a risk for the product

Do not store the product near sterilizing agents.

Do not expose this product to Steam, Dry Heat or any sterilization processes other than Gamma Radiation.

Do not reuse the sterilizer until the indicator has changed into the color indicated in the product.